510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY TEMPLATE

A. 510(k) Number:
K030263

B. Instrument Name:
Immunicon *CellTracks*™ Analyzer

C. System Descriptions:

1. Modes of Operation:
   Scanning Mode and Imaging Mode
2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:
   Yes ____X____ or No _____

   In lieu of a Hazard Analysis Immunicon submitted a Risk Analysis which conforms to ISO 14971, ISO: Medical Devices—Application of Risk Mangement to Medical Devices. Immunicon did submit software documentation which conforms to FDA's software documentation guidance document.

3. Sample Identification:
   The CellTracks Cartridge uses Bar Code labels
4. Specimen Sampling and Handling:
   Specimen sampling and handling is manual using Immunicon Cell Save sample preparation tubes.
5. Assay Types:
   Static cytometry
6. Reaction Types:
   Fluorescently labeled leukocyte subsets are immuno-magnetically selected and aligned in a scanning cytometer.
7. Calibration:
   Calibration is accomplished by running the Calibration test protocol each day of patient testing using the re-usable CellTracks Calibrator Cartridge which contains photo-stable fluorescent beads that are fixed in position in a solid matrix.
8. Quality Control:
   BD Multi –Check control liquid quality control reagents manufactured by Becton Dickinson are recommended to check the instrument, reagents, and operator technique

D. Other Supportive Performance Characteristics Data Not Covered In The "L. Performance Characteristics" Section Of The SE Decision Summary.

1. Clinical Testing:
   Accuracy was tested using NCCLS EP9-A, *Method Comparison and Bias Estimation Using Patient Samples.* Three geographically diverse clinical

study sites were used with blood samples from 149 HIV+ patients and 150 samples from normal donors. The Cell Tracks device was compared with the Becton Dickinson FACSCalibur System. Results of the testing indicated a slope of).95 and an R^2 of 0.9802 for CD4 and a slope of 0.77 and an R^2 of 0.9375 for CD3.

2. Nonclinical Testing:

a. Linearity: 0-2,000 cells/µl.
b. Precision: A 20 day precision study was performed according to NCCLS EP-5-A, *Evaluation of Precision Performance of Clinical Chemistry Devices* using three CellTracks Analyzers and Becton Dickinson BD Multi-Check Controls. The normal CD3 control within-run CV's ranged from 3.68% to 4.34%. The low CD3 control within-run CV's ranged from 3.89% to 6.60%.
c. Interference Testing: Lipid levels from 0 to @ 5,000 mg/dL, hematocrits from 43.3 to 76.2%, platelet counts from 210 x 10^3 to 2,040 x 10^3, and free hemoglobin in plasma levels of 10.3 to 12.4 g/dL had adverse affect on the CD3 or CD4 counts.

E. Other Supportive Information:

1. Intended Use: The intended use of the CellTracks device is to enumerate fluorescently labeled leukocyte subsets that are immuno-magnetically selected and aligned.

2. Principles of Operation: The CellTracks analyzer is used in conjunction with reagents containing ferrofluids and fluorescent labeled monoclonal antibodies. Ferrofluid consists of a magnetic core surrounded by a polymeric layer coated with antibodies for capturing target cells. In this example, all leukocytes are immuno-magnetically labeled by targeting the CD45 antigen. Ferrofluid particles are colloidal (75-100 nanometers in radius) and when mixed with a sample containing the target white blood cells, the anti-CD45 monoclonal antibodies conjugated to the ferrofluid (anti-CD45 ferrofluid) bind with the CD45 antigen associated with the white blood cells. Fluorescent reagents (Becton Dickinson reagents, and anti-CD3-APC and anti-CD4-PE, are added for identification and enumeration of cell subsets. The reagent/sample mixture is dispensed into a CellTracks Cartridge that is inserted into a MagNest, a fixture of two magnets yoked together by steel. The strong magnetic field causes the labeled target cells to move to the surface of the cartridge, where the CellTracks analyzer uses compact disk (CD) technology to focus and track along nickel lines on the surface of the Cell Tracks Cartridge and to analyze the fluorescent signatures of aligned cells. The software enumerates and classifies cell subsets based on fluorescence.

3. Regulation Number: 21 CFR 864.5220, Automated differential cell counter

4. Device Classification: Class II

5. Classification Panel: Hematology and Pathology Devices Panel (81)

6. Product Code: GKZ

F. Conclusion:

The Immunicon CellTracks Analyzer has been shown to be substantially equivalent to the Becton Dickinson FACSCalibur System (K840195).